K130325

DEC 2 4 2013

510(k) Summary

1. Applicant

Applicant Name: SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.
Address: 2/F West, M-7 Sinosteel Building, Maqueling Estate, Hi-Tech Industrial Park, Nanshan District, Shenzhen 518057, China

Contact person:
Name: Xie Qiongyu
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Date Prepared: 2013-1-30

2. Device information

- Trade name: Arm automatic blood pressure monitor
- Model No.: BF1110, BF1112, BF1113 and BF1115
- **Regulation Description**: Noninvasive blood pressure measurement system.
- Regulation Number: 21 CFR **870.1130**
- Product Code: **DXN**
- Class: II
- Review Panel: Cardiovascular
- **Indications for Use:** It is intended for measuring adult blood pressure and pulse rate over-the-counter.

3. Predicate Devices

- Noninvasive blood pressure measurement system
- **K-number:** K121932
- **Product Code: DXN**
- **Intended User**
  Over the counter
- **Patient Population**
  This device is intended for use on adults
- **Indications for Use:**
  The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.
  The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
- **Manufactured by:**
  Omron Healthcare, Inc.

4. Description of the device

Arm automatic blood pressure monitor is based on pressure vibration method. Blood pressure cuff use the air pump to inflate, then the arteries are extruded by the cuff with pressure. Pressure sensor collects the pressure in the cuff, and then converts it to digital signal to the CPU. Then the software calculates the systolic and diastolic blood pressure and pulse rate.

The arm automatic blood pressure monitor BF1110, BF1112, BF1113 and BF1115 have the same basic principles, main function, performance and intended use, and they are consistent in product structure and material.

5. Testing data and Clinical study

Laboratory testing was conducted to validate and verify that Arm automatic blood pressure monitor met all requirements of related international standards, including electrical safety, EMC, biocompatibility, specification. Results of these tests demonstrate compliance to the requirements of the bellow consensus standards.
Clinical study has been evaluated according to ANSI/AAMI SP10.

Applied Standard:
Electrical Safety and performance requirements: IEC 60601-1 AAMI performance standard ANSI/AAMI SP10
Home-used medical equipment requirements and Environmental test: IEC 60601-1-11
Electromagnetic Compatibility Requirements: EN 60601-1-2
Biocompatibility Evaluation for NIBP Cuff ISO 10993-1, ISO 10993-5, ISO 10993-10
Clinical Evaluation: ANSI/AAMI SP10

6. Comparison to Predicate Devices

Items	**Arm automatic blood pressure monitor**		**Noninvasive blood pressure measurement system**
Manufacture	SHENZHEN PUMP MEDICAL SYSTEM CO., LTD.		Omron Healthcare, Inc.
Model / Specification	BF1110 & BF1112	BF1113 & BF1115	HEM-7200-Z (BP742)
Intended use	It is intended for measuring adult blood pressure and pulse rate.		The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.

			The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
Patient population	Adult		Adult
Environment of use	Home		Home
Measuring Principle	Oscillometric Method		Oscillometric Method
Measurement Range	Pressure: 0mmHg~280mmHg (0kPa~37.3kPa) Pulse Rate: 40bpm ~ 180bpm		Pressure: 0mmHg~299mmHg Pulse Rate: 40bpm ~ 180bpm
Accuracy	Pressure:±3mmHg (±0.4kPa) Pulse Rate: ±5%		Pressure:±3mmHg (±0.4kPa) or 2% of reading Pulse Rate: ±5%
Display	TN-LCD Digital Display	BF1113: VA-LCD Digital Display BF1115:TN-LCD Digital Display	LCD
Memory	90 sets memory of measurement values	50 sets of measurement values (blood pressure and pulse rate) for each user (Memory1 and Memory 2)	30 sets of measurement values (blood pressure and pulse rate) for each user (A and B)
Power Source	4 AA Alkaline battery or AC Adaptor (AC 100~240 V)	4 AAA Alkaline battery or AC Adaptor (AC 100~240 V)	4 AA batteries or AC Adaptor (AC 100~240 V)
Operating Environment	Temperature: +5℃~+40℃; Humidity: ≤93%RH		Temperature: +10℃~+40℃; Humidity: 30 to 85%RH
Storage and Transport Environment	Temperature: -25℃~+70℃; Humidity: 10%~95%		Temperature: -25℃~+60℃; Humidity: 10%~95%
Weight	294g (Without batteries)	270g (Without batteries)	340g (Not Including batteries)
Size	140mm×110mm×70mm		141mm×123mm×85mm

The subject device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device.

7. Conclusion

As stated above, the Arm automatic blood pressure monitors (Models: BF1110, BF1112, BF1113 and BF1115) are safe and effective, and comply with the appropriate medical device standards. And they are substantially equivalent to the earlier identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

Shenzhen Pump Medical System Co., Ltd.
c/o Ms. Ivy Chen, Shenzhen Huatongwei International Inspection Co., Ltd.
Keji Nan No. 12 Road, Hi-tech Park
Shenzhen, Guangdong
CHINA 518057

Re: K130325
Trade/Device Names: Arm Automatic Blood Pressure Monitor, with models BF1110, BF1112, BF1113 and BF1115
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 3, 2013
Received: December 12, 2013

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

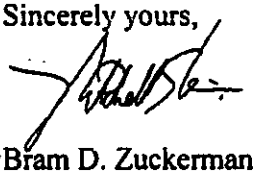
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K130325_____

Device Name: __Arm automatic blood pressure monitor_____

Indications for Use:

It is intended for measuring adult blood pressure and pulse rate.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use √ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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